Amendments to the Claims

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims

1. (original) A method of treating an impaired neurological function of an individual who has sustained a brain injury comprising administering to said individual an effective amount of apomorphine.

2. (original) The method according to Claim 1, wherein said impaired neurological function is an impaired cognitive function, an impaired motor function, or a combination of impaired cognitive and motor functions.

3. (original) The method according to Claim 1, wherein said impaired neurological function is an altered consciousness state (ACS) or amnesia.

4. (original) The method according to Claim 3, wherein said altered consciousness state is an ACS disorder.

5. (original) The method according to Claim 4, wherein said ACS disorder is selected from the group consisting of coma, near-coma, vegetative state, persistent vegetative state, and minimally conscious state.

6. (original) The method according to Claim 4, wherein said individual is administered apomorphine in an amount and for a period sufficient to stimulate an improvement in a pattern of consciousness within an altered consciousness state or in a change from a lower to a higher state of consciousness.

7. (original) The method according to Claim 6, wherein said improvement is indicated by improvement in a neurological function selected from the group consisting of circadian rhythm, eye opening, directed eye movement, directed body movement, response to verbal commands, communication ability, response to sensory stimulation, and combinations thereof.

8. (original) The method according to Claim 6, wherein said improvement is a change from a lower to a higher state of consciousness.

9. (original) The method according to Claim 8, wherein said higher state of consciousness is the state of full consciousness.

10. (original) The method according to Claim 6, wherein said improvement in a pattern or state of consciousness is determined using a protocol selected from the group consisting of Glasgow Outcome Scale, Extended Glasgow Outcome Scale (GOS-E), the Kennedy Johnson Scale, the Disability Rating Scale, the Coma-Near Coma Scale, Ranchos Amigos Scale, clinical impressions of change, and combinations thereof

11. (original) The method according to Claim 1, wherein said apomorphine is administered to said individual by a parenteral route.

12. (original) The method according to Claim 11, wherein said parenteral route is selected from the group of consisting of a subcutaneous route, an intravenous route, an intramuscular route, a transdermal route, a nasal route, and an inhalation route.

13. (original) The method according to Claim 11, wherein said apomorphine is administered to said individual by a parenteral route in a single dose using a syringe device or in a continuous infusion using a pump.

14. (original) The method according to Claim 1, wherein said apomorphine is administered to said individual by an enteric route along the alimentary canal.

15. (original) The method according to Claim 14, wherein said enteric route is selected from the group consisting of oral administration, sublingual administration, administration to the stomach by a tube, and rectal administration.

16. (original) The method according to Claim 1, wherein said brain injury is the result of an event selected from the group consisting of traumatic brain injury (TBI), a hypoxic event, an anoxic event, an ischemic event, organ failure, and a drug-induced brain injury.

17. (original) The method according to Claim 16, wherein said ischemic event is a stroke.

18. (original) The method according to Claim 16, wherein said TBI is the result of a fall on a surface or a vehicle accident.

19. (original) The method according to Claim1, wherein said individual is administered apomorphine for a period sufficient to promote an improvement in the functional independence of the individual.

20. (original) The method according to Claim 19, wherein said improvement in the functional independence of said individual is indicated by improved communication ability, improved motor ability, improved ability for daily self care, and combinations thereof.

21. (original) The method according to Claim 1, further comprising administering to said individual an additional dopaminergic agent.

22. (original) The method according to Claim 21, wherein said additional dopaminergic agent is selected from the group consisting of dopamine agonist, dopamine transport inhibitor, dopamine metabolism inhibitor, dopamine precursor, and combinations thereof.

23. (original) The method according to Claim 21, wherein said additional dopaminergic agent is capable of crossing the blood brain barrier.

24. (original) The method according to Claim 21, wherein said additional dopaminergic agent is administered to said individual by a parenteral or an enteric route.

25. (original) The method according to Claim 24, wherein said enteric route is via a nasojejunal tube or a gastrostomy tube.

26. (original) The method according to Claim 21, wherein said additional dopaminergic agent is selected from the group consisting of L-dopa, bromocriptine, amantadine, pergolide, pramipexole, ropinirole, fenoldopam, cabergoline, rotigotine, lysuride, talipexale, 7-OH DPAT, quinpirole, SKF-38393, and combinations thereof.

27. (original) The method according to Claim 26, wherein said additional dopaminergic agent is L-dopa.

28. (original) The method according to Claim 27, wherein said L-dopa is administered at a dose that is less than 1000 mg/day.

29. (original) The method according to Claim 1, wherein said apomorphine is administered in conjunction with an anti-emetic agent.

30. (original) The method according to Claim 29, wherein said apomorphine is co-administered, concurrently administered, or sequentially administered with said anti-emetic agent.

31. (original) The method according to Claim 30, wherein said apomorphine is sequentially administered after administration of said anti-emetic agent.

32. (original) The method according to Claim 29, wherein said anti-emetic agent is selected from the group consisting of a peripheral dopamine antagonist, a phenothiazine agent, a benzamide agent, a serotonin antagonist, a histamine antagonist, a parasympathetic depressant, and a meclizine agent.

33. (original) The method according to Claim 29, wherein said anti-emetic agent is selected from the group consisting of domperidone, prochlorperizine, trimethylbenzamide hydrochloride, chlormeprazine, prochlorpemazine, and combinations thereof.

34. (original) The method according to Claim 33, wherein said anti-emetic agent is domperidone.

35. (original) The method according to Claim 1, wherein said apomorphine is a single stereoisomer.

36. (original) The method according to Claim 1, wherein said apomorphine is a racemic mixture of stereoisomers.

37. (original) The method according to Claim 1, wherein said apomorphine is an acid salt.

38. (original) The method according to Claim 37, wherein said acid is selected from the group consisting of HCl, HBr, acetic acid, and lactic acid.

39. (original) The method according to Claim 37, wherein said apomorphine is apomorphine hydrochloride.

40. (original) The method according to Claim 1, wherein said apomorphine is administered to said individual in conjunction with a central nervous system stimulant selected from the group consisting of pemoline, caffeine, amphetamines, modafinil, and combinations thereof.

41. (original) The method according to Claim 1, wherein said apomorphine is administered to said individual in combination with applying to said individual at least one sensory stimulus.

42. (original) The method according to Claim 41, wherein said sensory stimulus is selected from the group consisting of light, color, a visual scene, hot temperature, cold temperature, tactile stimulation, a smell, a taste, a sound, and combinations thereof.

43. (original) The method according to Claim 1, wherein said apomorphine is administered to said individual in conjunction with a procedure to provide electric and/or magnetic stimulation to the brain, said procedure selected from the group consisting of vagal nerve stimulation, cranial nerve stimulation by electrical pulse waveform, neuromodulation using a pulsed electrical stimulus, electroconvulsive therapy, trans-cranial magnetic stimulation (TMS), deep brain stimulation (DBS), and combinations thereof.

44. (original) The method according to Claim 1, wherein said apomorphine is administered to said individual in conjunction with having said individual perform or attempt to perform a task or exercise to restore an impaired neurological function.

45. (original) The method according to Claim 1, wherein said apomorphine is administered to said individual in an amount of 12 to 200 mg/day.

46. (original) The method according to Claim 1, wherein said apomorphine is administered to said individual in an amount of 48 to 128 mg/day.

47. (original) The method according to Claim 45, wherein said amount of apomorphine is administered to said individual over a period of 12 to 16 hours/day.

48. (original) A kit comprising apomorphine in one or more containers adapted for use in a pump for continuous infusion of said apomorphine and instructions for administering apomorphine by continuous infusion with a pump to treat an impaired neurological function in an individual who has sustained a brain injury.

49. (original) The kit according to Claim 48, further comprising said pump for administering said apomorphine in said one or more ampoules to said individual.

50. (original) A method of treating an impaired neurological function of an individual who has sustained a brain injury comprising administering to said individual a dose of at least 1000 mg of L-dopa per day.

51. (original) The method according to Claim 50, wherein said dose of L-dopa is selected from the group consisting of at least 1250 mg/day, at least 1500 mg/day, at least 1750 mg/day, at least 2000 mg/day, and at least 2500 mg/day.

52. (original) The method according to Claim 50, wherein said dose of L-dopa is in the range of from 1250 to 2500 mg/day.

53. (original) The method according to Claim 50, wherein said impaired neurological function is an impaired cognitive function, an impaired motor function, or a combination of impaired cognitive and motor functions.

54. (original) The method according to Claim 50, wherein said impaired neurological function is an altered consciousness state (ACS) or amnesia.

55. (original) The method according to Claim 54, wherein said altered consciousness state is an ACS disorder.

56. (original) The method according to Claim 55, wherein said ACS disorder is selected from the group consisting of coma, near-coma, vegetative state, persistent vegetative state, and minimally conscious state.

57. (original) The method according to Claim 55, wherein said individual is administered L-dopa in an amount and for a period sufficient to stimulate an improvement in a pattern of consciousness within an altered consciousness state or in a change from a lower to a higher state of consciousness.

58. (original) The method according to Claim 57, wherein said improvement is indicated by improvement in a neurological function selected from the group consisting of circadian rhythm, eye opening, directed eye movement, directed body movement, response to verbal commands, communication ability, response to sensory stimulation, and combinations thereof.

59. (original) The method according to Claim 57, wherein said improvement is a change from a lower to a higher state of consciousness.

60. (original) The method according to Claim 59, wherein said higher state of consciousness is the state of full consciousness.

61. (original) The method according to Claim 57, wherein said improvement in a pattern or state of consciousness is determined using a protocol selected from the group consisting of

the Glasgow Outcome Scale, the Extended Glasgow Outcome Scale (GOS-E), the Kennedy Johnson Scale, the Disability Rating Scale, the Coma-Near Coma Scale, the Ranchos Amigos Scale, clinical impressions of change, and combinations thereof

62. (original) The method according to Claim 50, wherein said brain injury is the result of an event selected from the group consisting of traumatic brain injury (TBI), a hypoxic event, an anoxic event, an ischemic event, organ failure, and a drug-induced brain injury.

63. (original) The method according to Claim 62, wherein said ischemic event is a stroke.

64. (original) The method according to Claim 62, wherein said TBI is the result of a fall on a surface or a vehicle accident.

65. (original) The method according to Claim 50, wherein said individual is administered L-dopa for a period sufficient to promote an improvement in the functional independence of the individual.

66. (original) The method according to Claim 65, wherein said improvement in the functional independence of said individual is indicated by improved communication ability, improved motor ability, improved ability for daily self care, and combinations thereof.

67. (original) The method according to Claim 50, further comprising administering to said individual an additional dopaminergic agent.

68. (currently amended) The method according to Claim [[64]] 67, wherein said additional dopaminergic agent is selected from the group consisting of dopamine agonist, dopamine transport inhibitor, dopamine metabolism inhibitor, dopamine precursor, and combinations thereof.

69. (original) The method according to Claim 67, wherein said additional dopaminergic agent is capable of crossing the blood brain barrier.

70. (original) The method according to Claim 67, wherein said additional dopaminergic agent is administered to said individual by a parenteral or an enteric route.

71. (original) The method according to Claim 70, wherein said enteric route is via a nasojejunal tube or a gastrostomy tube.

72. (original) The method according to Claim 67, wherein said additional dopaminergic agent is selected from the group consisting of apomorphine, bromocriptine, amantadine, pergolide, pramipexole, ropinirole, fenoldopam, cabergoline, rotigotine, lysuride, talipexale, 7-OH DPAT, quinpirole, SKF-38393, and combinations thereof.

73. (original) The method according to Claim 72, wherein said additional dopaminergic agent is apomorphine.

74. (original) The method according to Claim 50, wherein said L-dopa is administered in conjunction with an anti-emetic agent.

75. (original) The method according to Claim 74, wherein said L-dopa is co-administered, concurrently administered, or sequentially administered with said anti-emetic agent.

76. (original) The method according to Claim 75, wherein said L-dopa is sequentially administered after administration of said anti-emetic agent.

77. (original) The method according to Claim 74, wherein said anti-emetic agent is selected from the group consisting of a peripheral dopamine antagonist, a phenothiazine agent, a benzamide agent, a serotonin antagonist, a histamine antagonist, a parasympathetic depressant, and a meclizine agent.

78. (original) The method according to Claim 74, wherein said anti-emetic agent is selected from the group consisting of domperidone, prochlorperizine, trimethylbenzamide hydrochloride, chlormeprazine, prochlorpemazine, and combinations thereof.

79. (original) The method according to Claim 78, wherein said anti-emetic agent is domperidone.

80. (original) The method according to Claim 50, wherein said L-dopa is administered to said individual in conjunction with a central nervous system stimulant selected from the group consisting of methylphenidate, pemoline, caffeine, amphetamines, modafinil, and combinations thereof.

81. (original) The method according to Claim 50, wherein said L-dopa is administered to said individual in combination with applying to said individual at least one sensory stimulus.

82. (original) The method according to Claim 81, wherein said sensory stimulus is selected from the group consisting of light, color, a visual scene, hot temperature, cold temperature, tactile stimulation, a smell, a taste, a sound, and combinations thereof.

83. (original) The method according to Claim 50, wherein said L-dopa is administered to said individual in conjunction with a procedure to provide electrical and/or magnetic stimulation to the brain, said procedure selected from the group consisting of vagal nerve stimulation, cranial nerve stimulation by electrical pulse waveform, neuromodulation using a pulsed electrical stimulus, electroconvulsive therapy, trans-cranial magnetic stimulation (TMS), deep brain stimulation (DBS), and combinations thereof.

84. (original) The method according to Claim 50, wherein said L-dopa is administered to said individual in conjunction with having said individual perform or attempt to perform a task or exercise to restore an impaired neurological function.

Claims 85-88 (canceled)